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Commissioner of Patents
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Re : International Application No. PCT/CA2005/000217
Filed on February 18th, 2005
Title : METHOD AND DEVICE USING MYOELECTRICAL ACTIVITY FOR
OPTIMIZING A PATIENT'S VENTILATORY ASSIST
Applicant : MAQUET CRITICAL CARE AB et al.
Our file : 08831-012

Dear Sirs:

This is in response to the Note on Informal Communication with the Applicant dated April 25, 2006.

In this communication, the Examiner refers to several passages of documents D1 and D2 and asserts that these documents teach and/or imply reduction of respiratory fatigue. These passages will be discussed in the following comments.

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Reference is first made to document D2, page 26, first paragraph. More specifically, this paragraph reads as follows:

"Furthermore, other increases in EMGdi signal amplitude, its integrals or derivatives or combinations thereof, detected via an EMG recording of the diaphragm or other muscles associated with inspiration above a desired threshold level and exceeding a desired duration, can be used to indicate the onset of an inspiratory effort."

It is respectfully submitted that this paragraph does not refer to respiration muscle fatigue, as contended by the Examiner, but to detection of the beginning of an inspiratory effort by the patient. It is interesting to note that in the third paragraph of page 26 of document D2, it is stated that the detected myoelectrical signal is compared

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to a predetermined threshold, not a calculated threshold as recited in the claims of the present patent application.

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The Examiner then states that document D2 deals with controlling air pressure into the lungs which is directly related to respiration muscle fatigue and refers to document D2, page 2, line 21. This paragraph reads as follows:

"Methods and systems according to the present invention further allow to reduce the problems related to the interface and the leaks occurring between the respiratory airways and ventilator circuit during the entire (or parts of) the period of neural inspiratory activation, which help to ensure adequate delivery of gas flow, volume and/or pressure into the lungs."

It is not clear to the applicant how the Examiner concludes that document D2 can potentially link air pressure control to respiration muscle fatigue. Not only this passage is silent on muscle fatigue but there is no indication that the air pressure assist can eventually be adjusted to prevent muscle fatigue, for example by controlling the assist in relation to a calculated threshold of a respiration-related feature over which muscle fatigue develops.

* * * * *

The Examiner further indicates that page 2, line 26 of document D2 describes neural deactivation of inspiratory muscles. This corresponding paragraph reads as follows:

"Methods and systems according to the present invention also allow synchronizing the deactivation of the seal between the respiratory airways and ventilator circuit with the neural deactivation of inspiratory muscles."

Therefore, this paragraph does not describe neural deactivation of inspiratory muscles but merely states that the methods and systems as described in document D2 allow synchronizing between the deactivation of the seal and the neural deactivation of the inspiratory muscles. Applicant see in this passage no relation with muscle fatigue; synchronizing deactivation of the seal with neural deactivation of the inspiratory muscles have no relation with muscle fatigue.

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Reference is then made to page 25, line 25 of document D2. The corresponding paragraph reads as follows:

"Even though step 102 has been described by referring to the measurement of myoelectrical activity of the diaphragm 24 using the system 10, the measurement of other respiratory-related EMG can be obtained with a suitable device placed in the vicinity of the respiratory related muscle, inserted or implanted on the surface of or into the muscle of interest."

In other words, this paragraph generally states that other muscles can be used to obtain respiratory-related EMG signals. The next two citations of the Examiner:

"The myoelectrical activity of these muscles can eventually be detected by means of electrodes directly implanted in the muscle" (page 31 of document D2)

" ... it should be kept in mind that the concept of the present invention can be used with any respiratory muscle signal" (page 3 of document D1)

are similar and deal with the detection of myoelectrical activity of the muscles.

The present invention is not concerned with the detection of a respiratory-related EMG signal but with the control of ventilatory assist based on a calculated threshold of a respiratory-related feature to prevent muscle fatigue as recited in the claims presently on file.

The Examiner's statement that "by controlling airway inspiratory flow and/or pressure, the risk of respiratory muscle fatigue is reduced" is respectfully traversed. Unappropriate control of airway inspiratory flow and/or pressure can even cause muscle fatigue.

Applicant is not trying to protect the prevention of respiratory muscle fatigue, but a method and device capable of achieving this result. For that purpose, a respiratory muscle fatigue critical threshold of a respiration-related feature is calculated and a level of ventilatory assist is controlled as a function of this calculated critical threshold in view of preventing fatigue of the respiratory muscle.

Document D1 is silent as to the manner used to determine the limit used to control the ventilatory assist and document D2 indicates at page 26 that the threshold is determined either by manual adjustment or automatically by letting the threshold be



relative to the mean noise level. In either case, these documents do not discuss respiratory muscle fatigue and methods and devices to prevent it. More specifically, it is respectfully submitted that neither documents D1 or D2, nor combinations thereof teach the calculation of a respiratory muscle fatigue critical threshold of a respiration-related feature and the control of a level of ventilatory assist as a function of this calculated critical threshold in view of preventing fatigue of the respiratory muscle.

In view of the above remarks, reconsideration of the present international patent application is respectfully requested.

Yours very truly,

BKP GP (BROUILLETTE KOSIE PRINCE)

A handwritten signature in dark ink, appearing to read 'Gaétan Prince', written over a horizontal line.

Gaétan Prince

GP/ML